REMARKS:

Reconsideration of the rejections set forth in the Final Office Action mailed July 20, 2009 and entry of the present amendment is requested because Applicants respectfully submit that the present Amendment places the application in condition for allowance or in better form for consideration on appeal.

In the Final Office Action, claims 1, 6-7, 25, and 28-30 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,045,570 ("the Epstein reference") in view of U.S. Publication No. 2002/ 0193808 ("the Belef reference"), claims 2-5 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Epstein reference in view of the Belef reference and further in view of U.S. Patent No. 5,626,601 ("the Gershony reference"), claims 8-10 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Epstein reference in view of the Belef reference and further in view of U.S. Patent No. 6,562,059 ("the Edwards reference"), claims 21-23 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Gershony reference, claim 24 was rejected under 35 U.S.C. § 103(a) as unpatentable over the Gershony reference in view of the Belef reference, and claims 26-27 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Epstein reference in view of the Belef reference and further in view of U.S. Patent No. 6,162,240 ("the Cates reference").

Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

First, as explained in Applicants' previous response filed on July 25, 2008, the Epstein reference discloses a closure device 21 that includes a tubular member 22 including a main lumen

26 and a second lumen 27 communicating with a port 28 on the distal extremity 24. Col. 4, line 66 to col. 5, line 13. A closure assembly 32 is carried by the distal extremity 24 of the tubular member 22 and is coupled to a deployment mechanism 33 for movement from a contracted to an expanded position. Col. 5, lines 28-33. The deployment mechanism 33 includes a push-pull wire 41 extending from the closure assembly 32 out the proximal extremity 23 of the tubular member 22 and connected to a handle 44. Col. 5, line 65 to col. 6, line 10. A button 47 on the handle 44 is slidably mounted in a slot 49 for moving the closure assembly 32 between the contracted and expanded positions. Col. 6, lines 14-24. Thus, the handle 44 does not include a piston slidably disposed within a chamber nor a reservoir filled with inflation media. Instead, the closure device 21 merely includes a push-pull wire arrangement that moves the closure assembly 32 from the contracted to the expanded position.

The Epstein closure device 21 also includes biological sealant means 81 carried by the handle 44 and in communication with the second lumen 27 for delivering sealant components via the external port 28. Col. 7, lines 1215; col. 6, lines 28-43. During use, the closure device 21 is inserted into "a conventional over-lying sheath 111" already in a puncture 106 extending to a vessel lumen 104 with the closure assembly 32 in the retracted position. Col. 8, lines 59-60, col. 9, lines 6-10; FIG. 5A. Once the distal extremity 24 of the tubular member 22 is exposed in the lumen 104, the sheath 111 is withdrawn, and the button 47 is retracted to expand the closure assembly 32. Col. 9, lines 10-23, 36-44. The closure device 21 is then retracted until the closure assembly 32 contacts the vessel wall 103 to form a seal. Col. 9, lines 54-60; FIG. 5B.

A sealant 116 is then delivered through the second lumen 27 of the tubular member 22 and "through the exit port 28 which is adjacent the closure assembly 32." Col. 10, lines 35-44; FIG. 5C. Once the sealant has assumed the desired state, the button 47 is moved within the slot 49 to retract the closure assembly 32 back into the tubular member 22, and the closure device 21 is removed from the puncture 106. Col. 11, lines 3-16.

Turning to the present claims, claim 1 recites an apparatus for sealing a puncture extending through tissue that includes a tubular member having a proximal end, a distal end sized for insertion into the puncture, and a lumen extending between the proximal and distal ends; an elongate occlusion member slidably disposed within the tubular member, the occlusion member comprising a proximal end, and a distal end extending distally through an opening in the distal end of the tubular member; an expandable member on the occlusion member distal end; a delivery device coupled to the proximal end of the tubular member, the delivery device comprising a plunger that is advanceable to deliver a sealing compound into the tubular member lumen; and a retraction assembly coupled to the proximal end of the tubular member and to the occlusion member, the retraction assembly comprising a lock for securing the tubular member in a distal position relative to the occlusion member, and a trigger that is activated by advancement of the plunger to thereby disengage the lock, the retraction assembly being biased to retract the tubular member proximally relative to the occlusion member when the lock is disengaged.

As conceded on the first full paragraph on page 3 of the Final Office Action, the Epstein reference fails to disclose, teach, or suggest anything about a retraction assembly.

However, the Epstein reference is completely deficient to render the present claims obvious for other reasons as well. In paragraph 10 bridging pages 10 and 11, the Final Office asserts that the tubular member recited in claim 1 is met by 111. The Epstein reference expressly teaches that 111 is a ***conventional over-lying sheath*** 111, col. 8, lines 59-60, and that the sheath 111 is withdrawn completely from the puncture 106 either before or after deploying the closure assembly 32, col. 9, lines 21-30, FIG. 5B. In either case, however, sealant 116 is not delivered until the closure assembly 32 has established a good seal with the wall 103 of the puncture 106, col. 10, lines 25-32, i.e., after the sheath 111 has been completely withdrawn from the puncture.

Although the Epstein sheath 111 is arguably a tubular member, ***a delivery device*** comprising a plunger to deliver a sealing compound is not ***coupled to the proximal end*** of the sheath 111, as recited in claim 1. Instead, the Epstein sealant means 81 (the only structure including a plunger as part of syringe 86) is coupled to the handle 44 of the closure device 21, and never to the sheath 111. Thus, the sheath 111 cannot constitute the tubular member recited in claim 1 for this reason alone.

In addition, the Epstein reference does not disclose, teach, or suggest a delivery device coupled to the proximal end of the tubular member to ***deliver a sealing compound from the tubular member lumen*** nor ***out the distal end of the tubular member***, as recited in claim 1. As explained above, the Epstein sealing means 81 is coupled to the closure device 21 to deliver sealant 116 from a second lumen 27 of tubular member 22 through a port 28 on the distal extremity 24 of the tubular member 22. The Epstein reference does not teach or suggest delivering the sealant 116 through the sheath 111, and, in fact, the sealant 116 is incapable of

being delivered through the sheath 111 since the sealing means 81 is coupled to the tubular device 22 and not the sheath 111. Finally, the sealant 116 could not be delivered through the sheath 111 because the sheath 111 is already removed from the puncture 106 when the sealant 116 is delivered, as clearly shown in FIG. 5C.

These substantial differences should be readily apparent upon reviewing the annotated drawings from the Epstein reference below.

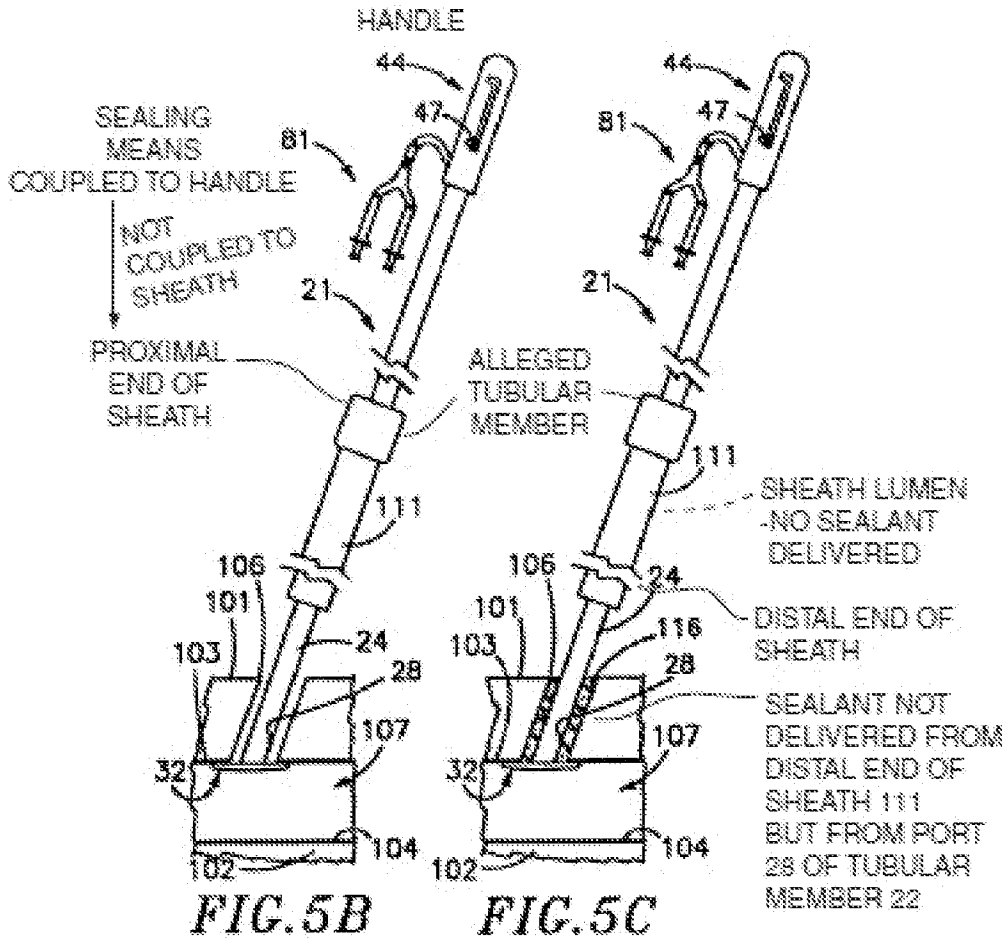

FIG. 5B FIG. 5C

Because none of the other references teaches or suggests a delivery device coupled to the proximal end of a tubular member, the delivery device comprising a plunger that is advanceable to deliver a sealing compound from the tubular member lumen out the distal end of the tubular member, claim 1 and its dependent claims are not obvious over the cited references for these reasons alone.

With respect to the retraction assembly recited in claim 1, the Final Office Action erroneously concludes on the paragraph bridging pages 3 and 4 that the Belef reference discloses a retraction assembly coupled to a tubular member 182 and an occlusion member 14 and that the alleged retraction assembly is biased to retract the tubular member [presumably 182] relative to the occlusion member [presumably 14]. These components of the Belef device cannot meet the features of claim 1 for at least three reasons, which will be explained with reference to FIG. 1 of the Belef reference annotated below.

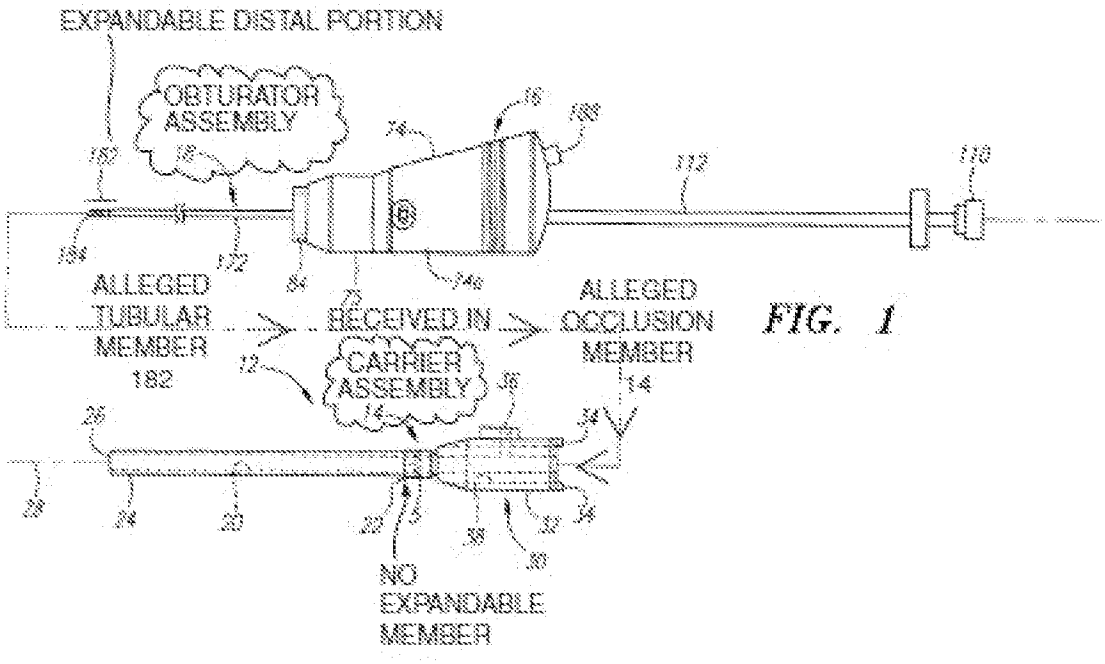

FIG. 1

First, the alleged occlusion member 14 of the Belef reference is not an occlusion member at all, but instead is a carrier assembly 14 for carrying a clip 5. Claim 1 recites that the occlusion member includes a proximal end, a distal end, and ***an expandable member on the occlusion member distal end***. As can been clearly seen in FIG. 1 above, the Belef carrier assembly 14 does not include an expandable member on the carrier assembly 14. The only arguable expandable member disclosed in the Belef reference is an expandable distal portion 182 of obturator assembly 18. However, the Final Office Action does not identify the expandable distal portion 182 as being the expandable member from claim 1 but identifies this expandable distal portion 182 as being the tubular member recited in claim 1.

Second, the Belef carrier assembly 14 cannot satisfy the occlusion member of claim 1 because the occlusion member of claim 1 is slidably disposed within the tubular member and the

occlusion member distal end extends distally through an opening in the distal end of the tubular member. The Final Office Action alleges that the tubular member of claim 1 is met by the expandable distal portion 182, which is part of obturator assembly 18. As can be clearly seen in FIG. 1 above, however, the obturator assembly 18 is inserted into sheath 12, which carries the carrier assembly 14, and not the other way around. Thus, the Belef carrier assembly 14 is incapable of being slidably disposed within the expandable distal portion 182 of the obturator assembly 18. As can be also seen in FIG. 1, the expandable distal portion 182 has an enclosed end 184 and does not have an opening through which anything, let alone the carrier assembly 14, could extend.

Finally, as explained in Applicants' previous response, the Belef device operates in a directly opposite manner to the retraction assembly recited in claim 1. Claim 1 recites that the retraction assembly is biased to ***retract the tubular member proximally relative to the occlusion member*** when the lock is disengaged ***while delivering sealing compound from the tubular member lumen*** out the distal end of the tubular member. As explained at page 72, lines 3-19 of the present application, when the retraction assembly is activated during use, the introducer sheath 90 (a tubular member, as claimed) may be automatically withdrawn proximally from the puncture 190 as the sealing compound 146 is delivered, thereby filling the puncture tract with the sealing compound 146, as shown in FIGS. 11E and 11F. Thus, while the occlusion member maintains temporary hemostasis, the tubular member is retracted proximally away from the occlusion member.

The only structure of the Belef reference that is remotely analogous to the sealing compound recited in claim 1 is the clip 5, since both are intended to seal or close a puncture. However, the clip 5 is carried by the carrier assembly 14, which is alleged to be the occlusion member of claim 1, and not the tubular member. The Belef reference does not teach moving the carrier assembly 14 proximally relative to the expandable distal portion 182, but advancing the carrier assembly 14 while collapsing and retracting the expandable distal portion 182. This is necessary to avoid driving the clip 5 carried by the carrier assembly 14 into splines 186 of the expanded distal portion 182.

Thus, in direct contrast to claim 1, the Belef reference discloses retracting the obturator assembly 18 (which is the only component that could arguably constitute an occlusion member as recited in claim 1) into a sheath 12. Thus, the Belef reference actually discloses advancing a tubular member relative to an occlusion member, and not retracting a tubular member, as does the retraction assembly of claim 1.

For these reasons, even if the Belef reference could somehow be properly combined with the Epstein reference, the result would be the opposite configuration of the apparatus of claim 1. However, the Epstein and Belef references cannot even be properly combined with one another, because, if the Epstein closure assembly 32 were retracted when sealant components were delivered (similar to the Belef apparatus collapsing and retracting the obturator assembly 18 while delivering the clip 5), the sealant components would simply pass through the puncture and enter the blood vessel. This would create substantial risk of embolism or other harm to the patient.

Thus, a person of ordinary skill would recognize that such automatic retraction during sealant delivery would clearly be undesirable and, in fact, dangerous to the patient.

For these reasons, claim 1 and its dependent claims are not obvious over the Epstein and Belef references. For similar reasons, claim 25 and its dependent claims are also not obvious over the Epstein and Belef reference.

The Cates reference cannot be properly combined with the other cited references and, even if somehow properly combined, fails to disclose, teach, or suggest the features wholly absent from the other cited references, as explained in Applicants' previous response. Finally, the Edwards reference also fails to provide any additional teaching or suggestion absent from the other cited references to render claims 1 and 25 and their dependent claims obvious.

Turning to the rejections based on the Gershony reference, as conceded in paragraph 6 on page 8 of the Final Office Action, the Gershony reference does not teach a piston. However, without any supporting evidence, the Final Office Action then concludes that "it was well known in the art that an inflation device or delivery comprises [sic] a plunger, piston or syringe activated by an actuator which may be connected to the inflation port 77 or injectate port 79, as taught by Gershony. Directing a plunger or piston proximally would cause" . . . . In the paragraph 12 bridging pages 11 and 12, this statement is repeated without any evidence to support the statement. Such cursory statements are not a clear articulation of the reasons why claim 21 is obvious and therefore fails to present a prima facie case of obviousness. Accordingly, for this reason alone, the rejections based on the Gershony reference should be withdrawn.

Turning to the actual language claim 21, an apparatus is recited for sealing a puncture extending through tissue that includes an outer member comprising proximal and distal ends defining a longitudinal axis therebetween with an inflation lumen extending between the outer member proximal and distal ends, an expandable member comprising proximal and distal ends and having a variable length dimension, the proximal end of the expandable member being coupled to the distal end of the outer member such that an interior of the expandable member is in fluid communication with the inflation lumen, the expandable member being expandable from a collapsed state to an expanded state by introduction of fluid into the interior; an inner member slidably coupled to the outer member and comprising proximal and distal ends, the inner member distal end coupled to the expandable member distal end, the inner member slidable relative to the outer member for moving the distal end of the expandable member towards and away from the proximal end of the expandable member when the expandable member is expanded and collapsed, respectively; and a housing on the proximal end of the outer member, the housing comprising a chamber in fluid communication with the inflation lumen, a piston slidably disposed within the chamber and coupled to the inner member, a reservoir filled with inflation media and in fluid communication with the chamber, and an actuator that may be activated by a user to direct the inflation media from the reservoir into the chamber and inflation lumen, thereby substantially simultaneously expanding the expandable member and directing the piston proximally to thereby pull the inner member proximally to shorten the expandable member as it expands.

First, the Gershony reference does not disclose, teach, or suggest anything about a housing on the proximal end of an outer member, the housing comprising a chamber in fluid communication with the inflation lumen, a piston slidably disposed within the chamber and coupled to the inner member, and a ***reservoir filled with inflation media*** and in fluid communication with the chamber.

Although the Gershony device 66 includes a hub 70 on a proximal end of shaft 69, the hub 70 does not include either a chamber or a reservoir filled with inflation media, as recited in claim 21, and, in particular, does not include a chamber ***and*** a reservoir, as claimed. The Final Office Action erroneously concludes that inflation port 77 of the Gershony hub 70 is a reservoir, but the inflation port 77 is merely a lumen 78 that extends from the inflation port 77 to the distal end of the shaft 69. This lumen 78 cannot constitute both a chamber and a reservoir, but is merely a single narrow passage used to deliver fluid to inflate balloon 71. Further, the lumen 78 cannot be a reservoir in any ordinary meaning of the word and clearly not as used in the present application. See, e.g., page 41, lines 5-15, FIGS. FIG. 12B.

In addition, it would not be obvious to add a piston in the lumen 78 of the Gershony reference, as erroneously stated in the Final Office Action. First, the lumen 78 is of insufficient size to receive a piston since it is intended merely to deliver fluid into balloon 71. Second, even if there were some reason a piston could be provided within the lumen 78 of the Gershony inflation port 77, such a piston could not be coupled to an inner member, as recited in claim 21. The Gershony core wire 73, although coupled to a tip 72 of balloon 71 could not be coupled to a

piston within the lumen 78 since the core wire 73 is disposed in a completely separate lumen 74 of its own.

Finally, the Gershony reference fails to disclose, teach, or suggest a housing that includes an actuator that may be activated by a user to ***direct the inflation media from the reservoir into the chamber*** and inflation lumen, thereby ***substantially simultaneously expanding*** the expandable member ***and directing the piston proximally*** to thereby pull the inner member proximally ***to shorten the expandable member as it expands***. Even if the Gershony lumen 78 and inflation port 77 could somehow constitute a chamber ***and*** a reservoir, neither the Gershony reference nor any of the other cited references disclose how an actuator could be provided on the Gershony hub 70 that would be capable of directing inflation media from one region of the lumen 78 to another to substantially simultaneously expand the balloon while also directing a piston proximally to pull the core wire 73 proximally to shorten the expandable member as it expands.

Unlike the claimed apparatus, the Gershony reference merely discloses a vascular sealing device 10 that includes a core wire 17 that may be manually proximally pulled to flatten a balloon 15. Col. 5, lines 41-62. Such manual manipulation introduces risk of user error, unlike the apparatus recited in claim 21, which substantially simultaneously expands and shortens (and conversely collapses and lengthens) an expandable member, as claimed. Thus, the claimed apparatus provides substantial advantages over the Gershony apparatus that are not well within the ordinary skill of the art based on the references of record. The only basis for concluding that claim 21 is obvious is the teachings of the present application, which constitutes improper hindsight.

Accordingly, for these reasons, claim 21 and its dependent claims are not obvious over the Gershony reference, either alone or if somehow combined with the other cited references.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,
VISTA IP LAW GROUP LLP

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By /william a. english/
William A. English
Reg. No. 42,515
Attorneys for Applicants

2040 Main Street, 9th Floor
Irvine, CA 92614
Telephone: (562) 665-3953
Facsimile: (949) 625-8955